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NOTICE OF ALLOWANCE AND FEE(S) DUE

26161 7590 08/28/2008

FISH & RICHARDSON PC
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MINNEAPOLIS, MN 55440-1022

EXAMINER

JARRETT, RYAN A

ART UNIT

PAPER NUMBER

2121

DATE MAILED: 08/28/2008

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/877,404

06/08/2001

Alan D. Ford

00786-157003 /

8082

TITLE OF INVENTION: INFUSION PUMP WITH AN ELECTRONICALLY LOADABLE DRUG LIBRARY AND LABEL READER

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1440 | \$300 | \$0 | \$1740 | 11/28/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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26161 7590 08/28/2008

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|--------------------|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/877,404 06/08/2001 Alan D. Ford 00786-157003 / 8082

TITLE OF INVENTION: INFUSION PUMP WITH AN ELECTRONICALLY LOADABLE DRUG LIBRARY AND LABEL READER

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|-------------|--------------|---------------|---------------------|----------------------|------------------|----------|
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nonprovisional NO \$1440 \$300 \$0 \$1740 11/28/2008

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|----------|----------|----------------|
|----------|----------|----------------|

JARRETT, RYAN A 2121 604-151000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 09/877,404 | 06/08/2001 | Alan D. Ford | 00786-157003 / MGH-0657.3 | 8082 |
| 26161 | 7590 | 08/28/2008 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | JARRETT, RYAN A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2121 | |
| DATE MAILED: 08/28/2008 | | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 996 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 996 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

09/877,404

Applicant(s)

FORD ET AL.

Examiner

Art Unit

Ryan A. Jarrett

2121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/05/08.
2. ☒ The allowed claim(s) is/are 96-111 and 115-122.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 08/05/08
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Ryan A. Jarrett/
Primary Examiner, Art Unit 2121

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The examiner's amendment was made since the previous title included a "user interface", but there is no claimed "user interface".

The application has been amended as follows:

The title was changed to:

**"AN INFUSION PUMP WITH AN ELECTRONICALLY LOADABLE DRUG
LIBRARY AND LABEL READER"**

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. This application has an effective filing date of October 15, 1992.

Response to Amendment

The rejection of claims 96-106 and 111-116 under 35 U.S.C. 112 1st paragraph (scope of enablement) has been withdrawn in light of the claim amendments filed 08/05/08.

The rejection of claims 96-122 under the grounds of nonstatutory obviousness-type double patenting has been withdrawn in light of the terminal disclaimer filed 08/05/08.

Terminal Disclaimer

The terminal disclaimer filed on 08/05/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,681,285 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

Claims 96-111 and 115-122 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Arthur III US 4,978,335 discloses configuring an infusion pump using drug information read from a drug container, wherein the drug information includes drug concentration. However, Arthur makes no mention at all of comparing this read drug information with a customized drug library comprising a drug entry and a corresponding set of drug delivery parameters, and if the read drug information matches the drug entry, configuring the infusion pump using the set of drug delivery parameters.

Coutre et al. US 5,153,827 discloses configuring an infusion pump using drug information read from a drug container, wherein the drug information includes drug concentration. Coutre et al. also discloses comparing this read drug information with prerecorded drugs in a pump database in order to determine allergy interactions (e.g., col. 10 lines 36-42). However, Coutre et al. makes no mention at all of comparing this read drug information with a customized drug library comprising a drug entry and a corresponding set of drug delivery parameters, and if the read drug information matches the drug entry, configuring the infusion pump using the set of drug delivery parameters.

Howson et al. US 5,088,981 discloses storing a customized drug library in a pump EEPROM (col. 6 lines 45-60), wherein the library comprises a drug entry and a corresponding set of drug delivery parameters (e.g., col. 13 lines 1-13). However, Howson et al. makes no mention at all of reading drug information on a container machine readable label and comparing

this drug information with the customized drug library, and if the drug information matches the drug entry, configuring the infusion pump using the set of drug delivery parameters.

Michaels et al. US 5,342,298 discloses reading syringe information from a syringe label and transferring the syringe information into a memory in the infusion pump, and comparing the syringe information with a syringe look up table comprising a syringe entry and a corresponding set of drug delivery parameters, and if the syringe information matches the syringe entry, configuring the pump using the set of drug delivery parameters. However, syringe information is not the same as drug information or drug identifier, and a syringe look up table or syringe library is not the same as a drug library, nor do they render obvious the drug information/drug identifier and/or drug library of the instantly claimed invention.

Specifically:

Per claim 96, the prior art of record fails to teach or fairly suggest “automatically comparing the drug information [read from the machine readable label] with a customized drug library comprising a drug entry and a corresponding set of drug delivery parameters; and if the drug information matches the drug entry, automatically configuring the infusion pump using the set of drug delivery parameters”, in combination with the remaining features and elements of the claimed invention.

Similarly, per claim 107, the prior art of record fails to teach or fairly suggest “means for comparing the drug information [read from the machine readable label] with a customized drug library comprising a drug entry and a corresponding set of drug delivery parameters to determine whether the drug information matches the drug entry; and means for configuring the infusion

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pump using the set of drug delivery parameters if the drug information matches the drug entry”, in combination with the remaining features and elements of the claimed invention.

Similarly, per claim 111, the prior art of record fails to teach or fairly suggest “one or more processors programmed to compare the drug information [read from the machine readable label] with the customized drug library [comprising a drug entry and a corresponding set of drug delivery parameters] to determine whether the drug information matches the drug entry; and configure the infusion pump using the set of drug delivery parameters if the drug information matches the drug entry”, in combination with the remaining features and elements of the claimed invention.

Similarly, per claim 117, the prior art of record fails to teach or fairly suggest “the processor is programmed to compare information from the machine readable label with information in the customized drug library to identify a drug entry that corresponds to the drug; and configure the drug infusion pump by using a set of drug delivery parameters associated with the drug entry in the customized library”, in combination with the remaining features and elements of the claimed invention.

Similarly, per claim 122, the prior art of record fails to teach or fairly suggest “means responsive to the label reader for identifying a drug entry in the customized drug library that corresponds to the drug; and means for configuring the processor by using the set of drug delivery parameters associated with the identified drug entry in the customized drug library”, in combination with the remaining features and elements of the claimed invention.

It is noted that the Examiner has reviewed the claims of US 6,269,340 for potential double patenting, but has not deemed any to exist.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan A. Jarrett whose telephone number is (571) 272-3742. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Decady can be reached on (571) 272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan A. Jarrett/
Primary Examiner, Art Unit 2121

08/25/08